Request for Approval Under the Generic Clearance for Emergency Epidemic Investigation Data Collections (0920-1011)

Instruction: This form should be completed by the primary contact person from the CDC CIO that will be sponsoring the investigation.

Determine if your investigation is appropriate for this Generic mechanism: *Instruction: Before completing and submitting this form, determine first if the proposed investigation is appropriate for the EEI Generic ICR mechanism. Complete the checklist below. If you select "yes" to all criteria in Column A, the EEI Generic IR mechanism can be used. If you select "yes" to any criterion in Column B, the EEI Generic ICR mechanism cannot be used.*

Column A	**Column B**
CDC epidemiological assistance is requested by one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authority or other partner organization). ☒ Yes ☐ No	The Investigation is initiated by CDC, without request from an external partner. ☐ Yes ☒ No
The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death). ☒ Yes ☐ No	The investigation is not urgent in nature. ☐ Yes ☒ No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. ☒ Yes ☐ No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. ☐ Yes ☒ No
One or more CDC staff (including trainees and fellows) will be deployed to the field. ☒ Yes ☐ No	CDC staff (including trainees or fellows) are not deployed to the field. ☐ Yes ☒ No
Data collection will be completed in 90 days or less. ☒ Yes ☐ No	Data collection expected to require greater than 90 days. ☐ Yes ☒ No

Did you select "Yes" to ***all*** criteria in Column A?

If yes, the EEI Generic ICR may be appropriate for your investigation. → You may proceed with this form.

Did you select "Yes" to ***any*** criterion in Column B?

If yes, the EEI Generic ICR is not appropriate for your investigation. → Stop completing this form now.

GenIC # 2014020 - XXX **Date** 09/25/14

Title of Investigation: *Instruction: Provide the title of the investigation in the following format: [Undetermined agent, undetermined source, undetermined mode of transmission, undetermined risk factor] for [disease/problem] among [subpopulation]—[State], [Year]*

Undetermined Sources and Risk Factors for an Ebola Virus Disease Outbreak—West Africa, 2014

Location of Investigation: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:

City/County (if applicable)

Country: West Africa: Sierra Leone, Guinea, Liberia, Nigeria, Senegal

Requesting Agency: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency: Ministry of Health & Sanitation, Sierra Leone

Name and Position Title: Dr. Brima Kargbo, Chief Medical Officer

Note: Attach the Letter of Invitation requesting support. The letter should include the following information: 1) background on the outbreak or event; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to inform prevention and control measures. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

Description of Investigation

1. Problem to be Investigated: *Instruction: Provide a summary of the outbreak or event. The summary should include all the information you know at this time about the outbreak or event and the investigation that is planned. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event, including a justification of the need for an investigation and why this issue requires an urgent response; 2) the objectives of the investigation, including how the information collected will be used to inform prevention and control measures; and 3) a brief overview of the investigation planned, including study design, respondents, mode of data collection. In the description, indicate whether a data collection instrument is attached with the GenIC request (refer to as Appendix 1, etc) and what instruments will be developed in the field. (suggested length: 250-500 words).*

On March 21, 2014, the World Health Organization and the Ministry of Health (MoH) of Guinea reported an outbreak of Ebola viral disease (EVD), and shortly thereafter clinical cases were also reported in Liberia. By May, the first cases identified in Sierra Leone were reported. The outbreak expanded to Nigeria on July 25th and Senegal on August 29th. The outbreak continues to accelerate in West Africa and is unprecedented in size. As of September 14th, there is a combined total of 5453 cases and 2624 deaths (case-fatality rate = 48%) reported in affected countries.

Major challenges faced by all partners in the efforts to control the outbreak include its wide geographic spread, weak health-care infrastructures, and community mistrust and resistance.

In June 2014, the World Health Organization, and the Ministries of Health in affected countries requested additional support from CDC and other partners, necessitating the deployment of CDC staff members to West Africa to aid in outbreak investigation and control.

In August, the World Health Organization declared the EVD outbreak an international public health emergency. Persistence and magnitude of the outbreak necessitates high-level, regional and international coordination to bolster response efforts among involved and neighboring nations and other response partners in order to control further infection and prevent outbreaks in other countries.Sierra Leone, Ministry of Health and Sanitation, has requested continued CDC assistance with the investigation to identify sources and risk factors for Ebola infection in order to implement specific prevention and control measures. As the initial outbreak expanded, country-specific GenICs were submitted and approved by OMB for data collections in Guinea (GenIC No. 2014010-XXX, exp. 9/25/2014), Liberia (GenIC No. 2014011-XXX, exp. 10/6/2014), and Sierra Leone (GenIC No. 2014-014, exp. 10/19/2014). As these GenICs have expired or will soon expire, an OMB International Emergency Clearance Package has been submitted to request OMB clearance for data collections related to basic epidemiological objectives. Data collected under the Emergency Clearance will be used to maintain a centralized database for data collected from all outbreak sites, and to assist in contact tracing, case report collection, and patient or family interviews. The Emergency Clearance includes already developed data collection forms to be used for well-defined data collection activities necessary for continued prevention and control measures.

This GenIC seeks OMB approval for additional urgent investigations necessary for prevention and control of the current EVD outbreak that were not included in the Emergency Clearance because final forms are not yet available. For example, prevention and control recommendations related to cultural practices and religious beliefs that influence disease transmission are needed; these factors are not well-understood. CDC will assist WHO and the ministries of health with an investigation of cultural and religious beliefs that influence disease transmission during home care and funerals of EVD cases. Data will be collected via observation and interviews with key informants, cases, and family members (draft form included in Appendices 1-3); these data collection instruments will be finalized in the field following initial observations. Because these data collections will be coordinated across multiple countries and will extend beyond the expiration of the currently approved GenICs, CDC is seeking approval for these new data collections in Sierra Leone, Guinea, Liberia, Nigeria, and Senegal under this new GenIC.

2. Characteristics of Outbreak or Event (Check all that Apply):

- ☐ Undetermined agent
- ☒ Undetermined source
- ☒ Undetermined mode of transmission
- ☒ Undetermined risk factor

3. Respondents: *Instruction: Select all that apply. For each respondent type selected, provide a brief description. Be sure to include a description of control respondents, if applicable. Use as much space as necessary for each description.*

- ☒ General public (describe):
  Persons who exhibit symptoms consistent with the case definitions of EVD or are at risk for infection (See Item 4 below)
- ☒ Healthcare staff (describe):
  Healthcare staff who exhibit symptoms consistent with the case definitions of EVD or are at risk for infection (See Item 4 below)
- ☐ Laboratory staff (describe):

☒ Patients (describe):

Persons who exhibit symptoms consistent with the case definitions of EVD or are confirmed cases (See Item 4 below)

☐ Restaurant staff (describe):

☒ Other (describe):

Key informants of cultural and religious practices, including government health officials, potential health consumers, village chiefs, and religious leaders.

4. Selection of Respondents: *Instruction: Provide a brief description of how respondents will be identified and selected. Use as much space as necessary for the description.*

Key informants for cultural and religious practices and beliefs will be interviewed. Key informants could be government health officials, health care workers, community members, village chiefs and religious leaders. These key informants will be selected by discussion with village chiefs and local health officials after identifying relevant at-risk and affected communities. Additional respondents could include persons who exhibit symptoms consistent with the case definitions of EVD or confirmed cases and contacts of family members of cases. Cases are categorized into one of three case definitions: suspected (alive or dead person with fever and at least three additional symptoms, or fever and a history of contact with a person with hemorrhagic fever or a dead or sick animal, or unexplained bleeding); probable (meets the suspected case definition and has an epidemiologic link to a confirmed or probable case); confirmed (suspected or probable case that also has laboratory confirmation). Exposure levels are defined by contact and interactions with known/suspect EVD cases or residence in an affected area.

5. Study Design: *Instruction: Select all that apply. For each study design planned, provide a brief description. Use as much space as necessary for the description.*

☒ Epidemiologic Study (indicate which type(s) below)

☒ Descriptive Study (describe):

- Determination of a valid risk reduction approach to decrease high risk exposure related to burial practices (see Appendices 1-3)

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☒ Other (describe):

- Other ancillary response efforts to provide data leading to outbreak control will also be carried out.

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

6. Data Collection Mode: *Instruction: Select all that apply. For each data collection mode planned, provide a brief description. Use as much space as necessary for the description.*

☒ Survey Mode (indicate which mode(s) below):

☒ Face-to-face Interview (describe):

Interview potentially exposed persons, cases and their contacts, as needed (See Appendices 1 and 3)

☐ Telephone Interview (describe):

☐ Self-administered Paper-and-Pencil Questionnaire (describe):

☐ Self-administered Internet Questionnaire (describe):

☒ Other (describe):

Observational assessments (See Appendix 2)

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ Environmental Sample:

☐ Other (describe):

7. Type of Information to be Collected: *Instruction: Select all that apply. For each type of information to be collected, provide a brief description. Use as much space as necessary for the description.*

☒ Behaviors (describe):

Behaviors related to cultural and religious beliefs that influence disease transmission during home care and funerals of EVD cases.

☐ Clinical information/symptoms (describe):

☐ Contact information (describe):

☐ Demographic information (describe):

☐ Environmental factors (describe):

☐ Exposures (describe):

☐ Medical history (describe):

☐ Risk factors (describe):

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
3 months

Research Determination: *Instruction: Indicate the research determination decision. If the decision is research, provide the research determination letter and IRB approval, if required.*

☐ Research ☒ Not Research

CDC Investigation Lead: *Instruction: Indicate the name, title, and affiliation of the person who will serve as the CDC lead for this investigation.*

Name: Barbara Knust

Title: Epidemiologist

Affiliation: NCEZID/DHCPP/Viral Special Pathogens Branch

CDC Sponsoring Program and Primary Contact Person: *Instruction: Indicate the sponsoring CIO/Division/Branch for this investigation. Indicate the name, title, and contact information of the CDC Primary Contact Person for this investigation. Indicate the preferred method of contact during the OMB approval process. Note, contact person or a designee must be available during the OMB approval process in case questions arise.*

CIO/Division/Branch: NCEZID/DHCPP/Viral Special Pathogens Branch

Name: Barbara Knust

Title: Epidemiologist

Contact Information: bknust@cdc.gov, 404-639-1104 email preferred

---

Certification: *Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the CDC Primary Contact Person for this Investigation.*

I, [insert name of CDC sponsoring program contact], certify the following to be true:

1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective prevention and control measures.

CDC Sponsoring Program Primary Contact Name: Barbara Knust

Date of Certification: 9/25/2014

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
EWB/DSEPD/CDC
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

For internal use. Do not complete.

Date/Time initial GenIC received by ICRL	9/22/2014, 4:48PM
Date/Time final GenIC received by ICRL	
Date/Time submitted to OMB	
Date/Time approved	
